

Appl. No. 10/785,985
Amendment dated: November 1, 2005
Reply to OA of: August 1, 2005

REMARKS

Applicants have amended the specification at page 6 to replace the term "phycocyanin" with the phrase "the total amount of C-phycocyanin and allophycocyanin." Additionally, at page 6, the phrase "in aforesaid oral prophylactic agent" has been replaced by the phrase "contained in said water-soluble formula". Support for these amendments may be found at, e.g., page 6, lines 14 through 16 of the specification as originally filed and original claim 13.

Applicants have amended the claims in order to more precisely define the scope of the present invention and address the objections to the claims and rejections to the claims under 35 U.S.C. §112 set forth in the outstanding Official Action.

Claims 5-8 and 10 have been canceled without prejudice or disclaimer.

With respect to the objection of claims 1-4, 16, 17 and 19 for using improper Markush group language, Applicants have amended claim 1 to no longer recite Markush group language. Claim 3 has been amended to recite proper Markush group language.

With respect to the rejection of claims 1-19 under 35 U.S.C. §112, first paragraph for failing to comply with the enablement requirement, Applicants have amended the claims to recite "An oral agent the prevents viral infection". Applicants respectfully assert that this claim language complies with the enablement requirement of §112, first paragraph. Applicants respectfully draw attention to page 2, line17 through page 3 line 20 of the present specification, wherein Applicants refer to several references that disclose that phycocyanin is capable of inhibiting enterovirus and influenza virus. Specifically, U.S. Patent No. 6,346,408 discloses that allophycocyanin is used as an anti-viral substance wherein the biological pigment is added in a method to inhibit enterovirus reproduction as well as influenza virus reproduction to prevent cytopathic effect (see, e.g., col. 1, lines 44-47). Therefore, Applicants respectfully assert that numerous literature sources support

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the enablement of the instant claims drawn to preventing viral infection.

With respect to the rejection of claims 3, 4, 6-11 and 14-18 under 35 U.S.C. §112, second paragraph, as being indefinite, Applicants have amended the claims to replace the use of the tilda with the phrase “to about”. Additionally, Applicants have amended claim 15 to rectify the lack of antecedent basis issue identified in the Official Action. The term “phycocyanin” has been replaced with the phrase “the total amount of C-phycocyanin and allophycocyanin”.

Additionally, Applicants have amended claims 1, 3, and 14 to clarify the water-soluble formula comprises 3 to about 45% C-phycocyanin, 1 to about 15% allophycocyanin and 96 to about 40% spirulina growth factor. The percentage of these components is only for water-soluble formula and not for the enteric-coated formula.

All of these amendments are clearly supported by the specification as originally filed. Applicants most respectfully assert that all claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claim 1, 2 and 16 under 35 U.S.C. §102(b) as being anticipated by Hirahashi and the rejection of claims 1, 2 17 and 19 under 35 U.S.C. §102(b) as being anticipated by Gemma have been carefully considered but are most respectfully traversed in light of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner’s attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as

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required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The Official Action urges that Hirahashi discloses that *Spirulina*, which naturally contains C-phycocyanin, allophycocyanin and spirulina growth factor, has anti-viral effects in humans and that the soluble extract was prepared from a spray-dried powder of *S. platensis* and therefore anticipates the claims of the present invention. Applicants respectfully traverse this statement.

The presently amended claims recite an oral agent that treats viral infection wherein the water-soluble formula comprises 3-45% C-phycocyanin, 1-15% allophycocyanin and 96-40% spirulina growth factor. To the contrary, Hirahashi fails to disclose an oral agent that comprises the claimed amounts of C-phycocyanin, allophycocyanin and spirulina growth factor. In fact, Hirashari fails to mention explicitly the presence of C-phycocyanin, allophycocyanin and spirulina growth factor in Spirulina. Thus, while Spirulina may naturally contain C-phycocyanin, allophycocyanin and spirulina growth factor, as urged in the Official Action, Hirashari makes no disclosure of their specific percentages within a composition and therefore clearly fails to anticipate Applicants invention as presently claimed. Accordingly, Applicants respectfully request that this rejection be withdrawn.

A similar shortcoming is found in Gemma. The Official Action urges that Gemma discloses administration of spirulina supplement to rats by blending the regular diet and spirulina into a dry powder and then administering by oral gavage with 0.5 mL of water or in rat chow. To the contrary, the present application claims an oral agent that treats viral infection wherein the water-soluble formula comprises 3-45% C-phycocyanin, 1-15% allophycocyanin and 96-40% spirulina growth factor. Like Hirashari, Gemma fails to disclose or even mention percentage ranges for C-phycocyanin, allophycocyanin and spirulina growth factor in a water-soluble formula. Therefore, Gemma also clearly fails to disclose the specific ranges of these components as claimed in the present invention. Accordingly, Applicants

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respectfully request that these rejections be withdrawn.

Further, with respect to Gemma, the reference fails to disclose an oral agent comprising a water-soluble or enteric-coated formula as claimed in the present invention. To the contrary, Gemma discloses supplementing a rodents diet with dry spirulina. No portion of Gemma discloses using the dry spirulina in a water-soluble or enteric-coated formula as presently claimed. Therefore, Gemma clearly fails to disclose every element of the present claims and cannot properly support a §102(b) rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over Hirahashi and Gemma has been carefully considered but is most respectfully traversed in light of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to the basic requirements of a *prima facie* case of obviousness as set forth in the MPEP § 2143. This section states that to establish a *prima facie* case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

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1988).

The Official Action urges that, while Hirahashi and Gemma fail to disclose a combination of water-soluble and enteric-coated forms of spirulina, it would have been obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose. The Official Action cites MPEP §2144.06 in support of this proposition. Applicants specifically traverse this statement.

While it may be *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose, this does not excuse the requirement of MPEP §2143 that the prior art references teach or suggest every element of the claimed invention. Thus, in order for MPEP §2144.06 to apply, the references must still disclose or suggest both the compositions that would be obvious to combine. This the prior art references of record fail to do.

Specifically, neither Hirahashi nor Gemma disclose an enteric-coated formula as claimed in the present invention. As discussed above, Gemma discloses dry spirulina delivered in powder form fed to animals, but makes no disclosure of an enteric-coated formula. Similarly, Hirahashi discloses hot water extract of Spirulina, but not an enteric-coated formula. Because neither of the prior art references relied upon in the Official Action disclose an enteric-coated formula, the combination of Gemma and Hirahashi fail to make a *prima facie* case of obviousness as required by MPEP §2143. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Additionally, as is stated in MPEP §2144.06, in order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958). Applicants respectfully assert that Gemma and Hirahashi do not disclose compositions used for the same purpose.

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Gemma discloses that aged rats fed dry spirulina have improved β -adrenergic receptor function, down-regulation of proinflammatory cytokines and decreased MDA in the cerebellum, and ultimately is concerned with combating aging. To the contrary, Hirahashi discloses orally administering hot water extract of Spirulina in order to activate the innate immune system and ultimately suppress cancer development and viral infection. Clearly, the prior art references do not disclose that the composition disclosed in each is useful for the same purpose.

Therefore, while it may be obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose as urged in the Official Action, the Official Action has failed to meet the requirements set forth in both §2144.06 and §2143 of the MPEP. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Official Action also urges that, while neither Gemma nor Hirahashi disclose the various concentrations of compounds claimed, differences in concentration or temperature will not support patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Further, the Official Action urges that it would have been obvious and well within the skill of the ordinary artisan to optimize the concentrations of spirulina and its components. Applicants respectfully traverse these statements.

Applicants note that neither Gemma nor Hirahashi disclose specific concentration ranges of C-phycocyanin, allophycocyanin and/or spirulina growth factor. In fact, both references deal exclusively with experiments conducted using Spirulina alone. While Spirulina may naturally contain C-phycocyanin, allophycocyanin and spirulina growth factor as urged in the Official Action, the absence of any detailed disclosure of these components in the references of record tends to refute the assertion that it would have been obvious to one of ordinary skill in the art to optimize the concentrations of said components. How would one even know to optimize the concentration of components that are not expressly disclosed in

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the prior art references or identified as having an effect on the results of the experimentation? Accordingly, Applicants respectfully request that this rejection be withdrawn.

Further, the present application contains claims directed to not only the concentration of C-phycocyanin, allophycocyanin and spirulina growth factor, but also to their composition ranges, the ratio of water-soluble formula to enteric-coated formula and ratio of the total amount of C-phycocyanin and allophycocyanin to spirulina growth factor. The Official Action makes no reference to these limitations and therefore fails to show where in the prior art references such limitations are disclosed. Further, Applicants assert that no such disclosure or suggestion exists in the prior art references. As discussed above, the prior art references discuss only the use of Spirulina and fail to address the components of C-phycocyanin, allophycocyanin and spirulina growth factor. Thus, Applicants assert that the references clearly fail to teach these specific limitations. Because neither Gemma nor Hirahashi, either standing alone or in combination, fail to disclose or suggest every element of the presently amended claims, the references cannot properly support a §103(a) rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Finally, Applicants respectfully assert that the ratio of water-soluble formula to enteric-coated formula recited in the present claims and the ration of the total amount of C-phycocyanin and allophycocyanin to spirulina growth factor recited in the present claims are novel and non-obvious. Applicants respectfully assert that it would not have been obvious to one of ordinary skill in the art to come to these ratios. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the

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application are most respectfully requested.

Respectfully submitted,

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